DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 22 2008

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the applications for patent term extension for the following U.S. Patents:

Product Name	U.S. Patent No.	Docket No.
Letairis	5,703,017	FDA-2008-E-0113
Letairis	7,109,205	FDA-2008-E-0110
Letairis	5,840,722	FDA-2008-E-0114
Letairis	5,932,730	FDA-2008-E-0103

The patent term extension applications were filed by Abbott Gmbh & Co. KG, under 35 U.S.C. § 156. The human drug product claimed by the patents is Letairis (ambrisentan), which was assigned new drug application (NDA) No. 22-081.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

The NDA was approved on June 15, 2007, which makes the submissions of the patent term extension applications on August 7, 2007, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patents are eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A), we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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